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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/966,119
Filing Date: September 28, 2001
Appellant(s): WEISBART ET AL.

Frank DiGiglio

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/18/05 appealing from the Office action mailed 7/29/04.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6171549	KENT	9-2001
EP 064210	HARDIE	11-82

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims.

A) Claims 8 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending Application No. 09/672911 in view of Hardie (EP 064210). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, the oral administration of the composition of claims 8 and 9 of copending Application No. 09/672911 with a carrier suitable for oral administration was known in the art at the time the invention was made (see Hardie, pages 3, lines 17-29, lines 34-41, page 4, lines 17-20).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

B) Claims 8 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie (EP 064210) in view of Kent (US Patent 6,171,549).

Hardie et al. teach a pharmaceutical composition comprising Cohn Fraction II and III (a blood derived product) and a pharmaceutically acceptable carrier suitable for oral administration (see pages 3, lines 17-29, lines 34-41, page 4, lines 17-20). Hardie does not teach that the composition is irradiated. The active ingredient in the composition is Ig (immunoglobulins, see page 4). Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation (see claims 1,12,13). Kent teaches that the products are irradiated to inactivate potential biological contaminants (see abstract and column 2, first complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Hardie et al. teach a pharmaceutical composition comprising blood product derived Cohn Fraction II and III and a pharmaceutically acceptable carrier suitable for oral administration whilst Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation. One of ordinary skill in the art at the time the invention was made would have been motivated to do the

aforementioned because Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation.

(10) Response to Argument

A) Claims 8 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending Application No. 09/672911 in view of Hardie (EP 064210).

Regarding appellants comments, although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, the oral administration of the composition of claims 8 and 9 of copending Application No. 09/672911 with a carrier suitable for oral administration was known in the art at the time the invention was made (see Hardie, (see pages 3, lines 17-29,lines 34-41, page 4, lines 17-20). In addition, Hardie discloses an immunoglobulin composition in claim 1 wherein Cohn Fraction II plus III has the desired concentration of IgG (at least 70% IgG, see page 4, lines 17-20).

B) Claims 8 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie (EP 064210) in view of Kent (US Patent 6,171,549).

Regarding appellants comments, Hardie, page 4, lines 17-20 teaches:

"Preferably, the instant oral composition will contain about 1-80% IG, more preferably about 5-50% of which not less than 70% is gamma globulin (IgG) as mentioned above. The product may contain other globulins such as IgA, IgM, IgD, and IgE. **For example, Cohn Fraction II and III contains the following proportions of the above: about 8 parts IgG to 1 part each of IgA and IgM and traces of IgD and IgE.".**

Thus, Hardie teaches the claimed oral composition of Cohn fraction II and III. In addition, claim 1 of Hardy indicates that the oral preparation comprises human blood fractionation derived Ig (Cohn fraction II and III is a human blood fractionation derived Ig) wherein at least 70% of the immunoglobulin is IgG and Hardie teaches that Cohn fraction II and III has the aformentioned properties (page 4, lines 17-20, wherein Cohn fraction II and III contain about 80% IgG). Regarding appellants comments about Cohn fraction as only a starting material for the oral composition of Ig, as per above, this line of reasoning is clearly erroneous. Regarding appellants comments, Hardie disclose that the preparation can be rendered hepatitis safe by "methods known in the art" (page 4, last paragraph). Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation (see claims 1,12,13). Kent teaches that the products are irradiated to inactivate potential biological contaminants including viruses (hepatitis is a virus) (see abstract and column 2, first complete paragraph). The claimed composition comprising Cohn fraction II and III can have additional ingredients in addition to Cohn fraction II and III. Regarding appellants comments about "orally

administrable by irradiation" (see page 6, 8 lines from the bottom) , the Examiner doesn't understand what this means.

The Cohn faction II and III is irradiated as a means to sterilize the blood product. It is not a form of administration. Regarding appellants comments, Hardie disclose the claimed composition as per above and Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation (see claims 1,12,13).

Regarding appellants comments about what is well known and accepted in the art, appellants comments carry zero weight. The MPEP section 716.01(c),) states:

ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

It is also noted that Kent discloses that irradiation can be used to sterilize foods, wherein foods are generally consumed orally (see column 13, last paragraph). As per above, Hardie disclose the Cohn II and III composition for oral administration. One of ordinary skill in the art at the time the invention was made would have been motivated to irradiate said composition because Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation. The orally administrable composition containing the blood product Cohn II and III was taught by Hardie. As per above, Hardie also taught the preparation can be rendered hepatitis safe by "methods known in the art". Appellants arguments in page 8, last paragraph of the Brief are based on zero evidence of record.

Appellants arguments about reasonable expectation of success are wrong because the orally administrable form of Cohn II and III was already taught by Hardie. Furthermore even though there is no evidence to support appellants conjectures, Kent disclose that radiation can be used to sterilize food products that are consumed orally.

Regarding appellants comments about "long-felt need", and the quoted passage of the specification, the treatment of Rheumatoid arthritis with oral IVIG (a composition that contains the same active ingredients as Cohns fraction II and III (aka IgG)) was already known in the art. In fact, it was the subject of US Patent already issued to Inventor Weissbart before the filing date of the instant application. In fact, when the terms rheumatoid arthritis or ra and treat? (treatment, treats, treatable, etc) are searched in WEST (US Patent and application database) with the near30 describer (the terms are within 30 words of each other) 25,592 hits are achieved.

Regarding appellants comments, Kent discloses that blood products, including proteins/antibodies can be sterilized via irradiation (see claims 1,12,13). Cohn fraction II and III is derived from blood products and contains active ingredients that are proteins/antibodies. The irradiation method taught by Kent is recited in the claims of an issued US Patent and therefore the claims are enabled for the scope of the method recited. Kent teaches that the blood products are irradiated to inactivate potential biological contaminants (see abstract and column 2, first complete paragraph).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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